

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION**

FRANCISCAN ALLIANCE, INC., *et al.*,

Plaintiffs,

v.

No. 7:16-cv-108

SYLVIA BURWELL, Secretary of the
United States Department of Health
and Human Services, *et al.*,

Defendants.

DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

Defendants Sylvia Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services, and the United States Department of Health and Human Services, hereby oppose Plaintiffs' motions for preliminary injunction. A memorandum of points and authorities is attached.

Dated: November 23, 2016

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MEMORANDUM OF POINTS AND AUTHORITIES
IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs, a group of states and religiously affiliated health care providers, seek a preliminary injunction to prevent the federal government from enforcing against them two aspects of a regulation that implements Section 1557 of the Affordable Care Act. As relevant here, Section 1557 prohibits sex discrimination in health care programs and activities that receive federal funds. 42 U.S.C. § 18116. After a robust notice-and-comment process, the Department of Health and Human Services interpreted Section 1557's prohibition on sex discrimination as encompassing discrimination on the bases of gender identity and termination of pregnancy. *See* United States Department of Health and Human Services (the "Department" or "HHS"), *Nondiscrimination in Health Programs and Activities* (the "Rule"), 81 Fed. Reg. 31,376, 31,388-89 (May 18, 2016) (codified at 45 C.F.R. § 92.4).

Plaintiffs' motions for preliminary injunction should be denied. First, Plaintiffs have failed to demonstrate irreparable harm. Their allegations of such harm rest on several misunderstandings about the effect and scope of the Rule. The critical point for present purposes is that, contrary to Plaintiffs' assertions, the Rule does not require any covered entity to perform, or to provide insurance coverage for, any particular medical services, but rather seeks to ensure that covered entities' actions are not the product of unlawful discrimination. In addition, Plaintiffs fail to acknowledge the Rule's built-in protections for medical judgment and religious and conscience-based objections. The Rule does not prevent health care professionals from expressing and exercising their good-faith, nondiscriminatory medical judgment. To the contrary, the Department explicitly acknowledged that "[s]cientific or medical reasons can justify distinctions based on" sex or other grounds on which discrimination is prohibited under the Rule. *Id.* at 31,405. Likewise, the Rule does not override federal statutory protections for religious freedom and conscience—including the Church, Weldon, and Coats amendments, and the Religious Freedom Restoration

Act—and it does not displace state laws concerning abortion. Quite the opposite, the Rule recognizes them. 45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379 & nn.12-14. Section 1557 and the Rule also incorporate extensive procedures for administrative and judicial review of any allegations of unlawful discrimination. Thus, only if the Court were to ignore the very protections that the Rule recognizes and the procedures the Rule provides could the Court credit Plaintiffs’ allegations of irreparable harm. Because the Court cannot do so, Plaintiffs cannot establish an imminent threat of irreparable injury, which is an essential prerequisite to a preliminary injunction. *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008).

For similar reasons, Plaintiffs are unlikely to succeed in this case because this Court lacks jurisdiction. When allegations are raised in a specific case that a covered entity has provided services or coverage in a discriminatory manner, the entity then has an opportunity to raise any objections pursuant to a comprehensive process that Congress has authorized for investigating and adjudicating such allegations—procedures that must be exhausted before a finding of unlawful discrimination can be made and federal financial assistance terminated. Until that time, Plaintiffs’ injuries are speculative, their claims are unripe, and they lack standing.

Even if the Court were to conclude that Plaintiffs have demonstrated irreparable harm and a basis for jurisdiction—and it should not—the Court still should deny Plaintiffs’ motions because Plaintiffs have failed to demonstrate a likelihood of success on the merits. Plaintiffs have not established that Section 1557’s prohibition against discrimination on the basis of sex refers solely to discrimination on the basis of biological or chromosomal traits, as opposed to also including discrimination motivated by other “sex-based considerations,” *Price Waterhouse v. Hopkins*, 490 U.S. 228, 242 (1989), such as the divergence between a person’s gender identity and his or her sex assigned at birth—*i.e.*, a person’s transgender status. Courts have generally comprehended the

Supreme Court’s broad understanding of the statutory concept of sex discrimination as encompassing discrimination based on gender identity, and the policies underlying the Affordable Care Act weigh in favor of the Department’s interpretation in the health care realm. Viewed through the familiar *Chevron* lens, the Department’s interpretation of Section 1557 as prohibiting discrimination against persons whose gender identity does not match their birth-assigned sex is reasonable and entitled to deference.

Defendants acknowledge that this Court recently concluded that the term “on the basis of sex” in a Department of Education regulation, *see* 34 C.F.R. § 106.33, unambiguously refers solely to “the biological and anatomical differences between male and female students as determined at their birth,” even where such a determination results in treating a transgender person inconsistently with his or her gender identity. *See Texas v. United States*, No. 7:16-cv-54, 2016 WL 4426495, at *14-15 (N.D. Tex. Aug. 21, 2016). Defendants respectfully disagree, but if the Court were to reach a similar conclusion about Section 1557’s prohibition on sex discrimination, it should not go further. *See Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 205 (2009) (“[I]t is a well-established principle governing the prudent exercise of this Court’s jurisdiction that normally the Court will not decide a constitutional question if there is some other ground upon which to dispose of the case.” (citation omitted)); *see generally United States v. Howell*, 838 F.3d 489, 493 n.13 (5th Cir. 2016) (collecting cases). In any event, Plaintiffs’ remaining claims are meritless for the reasons explained below.

Finally, the public interest and the potential harms to third parties outweigh Plaintiffs’ alleged injuries in this premature case. Plaintiffs cannot show that the balance of the equities is on their side. For all these reasons, Defendants respectfully request that the Court deny Plaintiffs’ motions for preliminary injunction.

BACKGROUND

I. Statutory And Regulatory Background

A. Section 1557 of the Affordable Care Act

In enacting Section 1557 of the Patient Protection and Affordable Care Act of 2010 (“Affordable Care Act” or “ACA”), Pub. L. No. 111-148, 124 Stat. 119, Congress built on a collection of well-settled federal antidiscrimination laws to guarantee full civil rights protections for federally funded and federally administered programs and activities in the health care sector. For decades, the federal government has promulgated and enforced laws designed to ensure that entities receiving federal funds do not discriminate. For example, Title VI of the Civil Rights Act of 1964 bars the recipients of federal funds from discriminating on the basis of race and national origin. 42 U.S.C. §§ 2000d *et seq.* (“Title VI”). Title IX of the Education Amendments Act of 1972 prohibits entities receiving federal funds from discriminating on the basis of sex in their education programs and activities. 20 U.S.C. §§ 1681 *et seq.* (“Title IX”). Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of disability in programs receiving federal financial assistance. 29 U.S.C. §§ 794 *et seq.* (“Section 504”). And the Age Discrimination Act of 1975 prohibits discrimination on the basis of age in programs receiving federal financial assistance. 42 U.S.C. §§ 6101 *et seq.* (the “Age Act”).

Invoking Title VI, Title IX, Section 504, and the Age Act, Section 1557 of the Affordable Care Act applies those four laws’ well-established prohibitions on discrimination—on the bases of race, color, national origin, age, sex, and disability—to federally funded health care programs and activities. Specifically, Section 1557 provides that

[e]xcept as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under [Title VI, Title IX, the Age Act, or Section 504], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or

contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA] (or amendments).

42 U.S.C. § 18116(a).

B. The Regulation Implementing Section 1557

Congress authorized the Secretary of HHS to “promulgate regulations to implement” Section 1557. 42 U.S.C. § 18116(c). Pursuant to that authority, the Department began its rulemaking process in August 2013, when its Office for Civil Rights (“OCR”) published a Request for Information in the Federal Register to solicit information on a number of issues arising under the statute. *See Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities*, 78 Fed. Reg. 46,558 (Aug. 1, 2013). In so doing, the Department emphasized that “Section 1557 builds on a landscape of existing civil rights laws,” noting that before its enactment, “the prohibitions against discrimination on the grounds of race, color, national origin, age and disability in Title VI, the Age Act, and Section 504, respectively,” already applied “to all programs and activities covered by those statutes, including those related to health.” *Id.* at 46,559. As to sex discrimination, because the applicability of Title IX itself is limited “to education programs and activities of covered entities[.]” the Department acknowledged that “Section 1557 is the first Federal civil rights statute that prohibits sex discrimination in health programs and activities of covered entities.” *Id.*

The Department issued a Notice of Proposed Rulemaking (“NPRM”) in September 2015. *Nondiscrimination in Health Programs and Activities*, 80 Fed. Reg. 54,172 (Sept. 8, 2015). As the Department explained,

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved

communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people's talent and energy.

Id. at 54,194 (footnote omitted); *see id.* at 54,194 n.103 (collecting authorities). The Department's proposed rule aimed to "help address these issues." *Id.* at 54,194.

In the NPRM, the Department proposed to define prohibited sex discrimination to include "discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, or gender identity." *Id.* at 54,176;¹ *see also id.* at 54,172 (noting that of the 303 comments HHS received from individuals in response to the Request for Information, "239 were personal testimonies from transgender individuals describing their experiences of discrimination in the health care setting"). In addition, while affirming that "a fundamental purpose of the ACA is to ensure that vital health care services

¹ In proposing this definition, the Department took account of federal agencies' and courts' conclusions that sex discrimination includes discrimination on the bases of gender identity and termination of pregnancy. *See* 81 Fed. Reg. at 31,384-85 & nn.42-43, 31,387-88 & nn.57-59; *see, e.g.,* Letter from Leon Rodriguez, Director, Office for Civil Rights, U.S. Department of Health & Human Services, to Maya Rupert (July 12, 2012) (Section 1557) ("Section 1557's sex discrimination prohibition extends to claims of discrimination based on gender identity"); *Mia Macy v. Eric Holder*, EEOC Appeal No. 0120120821, 2012 WL 1435995, at *7 (EEOC Apr. 20, 2012) (Title VII) ("When an employer discriminates against someone because the person is transgender, the employer has engaged in disparate treatment related to the sex of the victim." (citation omitted)); *Glenn v. Brumby*, 663 F.3d 1312, 1317-18 (11th Cir. 2011) (surveying decisions, dating to 2000, holding in various contexts that "discrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender"); *Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting From Federal Financial Assistance*, 40 Fed. Reg. 24,128, 24,142 (June 4, 1975) (Title IX) (defining sex discrimination to include discrimination on the basis of "termination of pregnancy") (now codified at, *e.g.,* 34 C.F.R. § 106.40 (Department of Education); 45 C.F.R. § 86.40(b) (HHS)).

are broadly and nondiscriminatorily available to individuals throughout the country,” the Department also sought “to ensure that the rule has the proper scope and appropriately protects sincerely held religious beliefs to the extent that those beliefs conflict with provisions of the regulation.” *Id.* at 54,173. The Department noted that the proposed rule would “not displace . . . protections afforded by provider conscience laws, the Religious Freedom Restoration Act, [and] provisions in the ACA related to abortion services,” *id.* (footnotes omitted); *see id.* at 54,173 nn.5-7, and specifically sought “comment on the extent to which [those] existing protections would provide sufficient safeguards,” *id.* at 54,173.

The Department issued its final rule on May 18, 2016. *See* 81 Fed. Reg. 31,376 (codified at 45 C.F.R. pt. 92).² As relevant here, the Rule implements Section 1557’s prohibition against sex discrimination, *see* 45 C.F.R. § 92.101, in “every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department,” *id.* § 92.2(a). The Rule defines sex discrimination as the Department proposed, *i.e.*, to “include[] . . . discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.” *Id.* § 92.4; *see* 81 Fed. Reg. at 31,387-90 (responding to comments on this definition and explaining

² Because all of Plaintiffs’ challenges are limited to the Rule’s definition of sex discrimination as encompassing discrimination on the bases of gender identity and termination of pregnancy, the discussion that follows is limited accordingly. Most provisions of the Rule are not challenged here, including: those concerning discrimination on the basis of race, color, national origin, age, and disability, *e.g.*, 45 C.F.R. § 92.101; those requiring the designation of a responsible employee and the adoption of grievance procedures, *id.* § 92.7; those concerning meaningful access for individuals with limited English proficiency, *id.* § 92.201, effective communication for individuals with disabilities, *id.* § 92.202, and accessibility standards for buildings and facilities, *id.* § 92.203, and for electronic and information technology, *id.* § 92.204; those prohibiting nondiscrimination on the basis of association, *id.* § 92.209; and the procedures for health programs or activities administered by the Department itself, *id.* § 92.303. The Rule also contains an express severability provision. *See id.* § 92.2(c).

the Department’s rationale). The Rule specifies that it “does not apply to employment,” except with regard to certain covered entities’ employee health benefit programs. 45 C.F.R. § 92.101(a)(2); *see id.* § 92.208; *see also id.* § 92.207.

Finally, the Rule confirms that “[i]nsofar as the application of any requirement under [the Rule] would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.” *Id.* § 92.2(b)(2); *see* 81 Fed. Reg. at 31,378-81 & nn.12-13, 31,388, 31,435. The Department also clarified that the Rule does not displace “provisions in the ACA related to abortion services.” 81 Fed. Reg. at 31,379; *see id.* at 31,379-80 & n.14, 31,388.

C. Plaintiffs’ Claims Concerning The Rule’s Prohibition On Sex Discrimination

Plaintiffs’ claims are limited to the Rule’s prohibition against sex discrimination (1) in the provision of health care services, and (2) in the provision of health insurance coverage. *See, e.g.,* Franciscan Br. 6-7, 10-12.³ As explained below, Plaintiffs misapprehend the Rule’s scope and what it does (and does not) require. At the outset, three general points deserve emphasis:

First, the Department has explicitly confirmed that under the Rule, “[s]cientific or medical reasons can justify distinctions based on” sex. 81 Fed. Reg. at 31,405. The Rule does not “seek[] to override . . . medical judgment.” Franciscan Br. 1.

Second, as with medical judgment, the Rule respects religious views. Because the Rule expressly incorporates “applicable Federal statutory protections for religious freedom and conscience,” 45 C.F.R. § 92.2(b)(2); *see* 81 Fed. Reg. at 31,379 & nn.12-13, no part of the Rule can be applied: so as to require any individual “to perform or assist in the performance of any part

³ Throughout, Plaintiffs’ filings are cited as follows: Compl. (Aug. 23, 2016), ECF No. 1; First Am. Compl. (Oct. 17, 2016), ECF No. 21; Pls.’ Brief in Support of Their Mot. (“Franciscan Br.”) (Oct. 21, 2016), ECF No. 25; Br. in Support of State Pls.’ Mot. (“States Br.”) (Oct. 21, 2016), ECF No. 23; App’x to Pls.’ Br. in Support of Their Mot. (“Pls.’ App’x”) (Oct 21, 2016), ECF No. 26; Supp. Brief in Support of Pls.’ Mot. (“Pls.’ Supp. Br.”) (Nov. 9, 2016), ECF No. 37.

of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions,” 42 U.S.C. § 300a-7(d) (“Church Amendment”); so as to “substantially burden a person’s exercise of religion” unless doing so “is the least restrictive means of furthering [a] compelling governmental interest,” *id.* § 2000bb-1(b) (Religious Freedom Restoration Act or “RFRA”); or so as to “discriminat[e]” against “any institutional or individual health care entity . . . on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions,” Pub. L. No. 114-113, Div. H, § 507(d), 129 Stat. 2242, 2649 (2015) (“Weldon Amendment”), *as incorporated*, Pub. L. No. 114-223, Div. C, 130 Stat. 857, 909 (2016).⁴ Accordingly, the Rule does not “attempt to force doctors to violate their religious beliefs.” Franciscan Br. 1.

Third, the Rule does not require any covered entity to perform, or to provide insurance coverage for, any particular medical service—whether related to gender transition, termination of pregnancy, or otherwise—but instead simply ensures that services are provided and covered in

⁴ *See also* 42 U.S.C. § 238n(a) (“Coats Amendment”) (“The Federal Government . . . may not subject any health care entity to discrimination on the basis that—(1) the entity refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions; [or] (2) the entity refuses to make arrangements for any of the activities specified in paragraph (1)”); *id.* § 300a-7(b) (Church Amendment) (“The receipt of any grant, contract, loan, or loan guarantee under [three specified federal funding streams] by any individual or entity does not authorize any court or any public official or other public authority to require—(1) such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions; (2) such entity to—(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any such sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.”). *See generally Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws*, 76 Fed. Reg. 9,968, 9,969-70 (Feb. 23, 2011) (providing an overview of the Church, Weldon, and Coats amendments).

nondiscriminatory ways. For example, consistent with the discussion above, the Rule does not state—nor has the Department ever stated—that the Rule requires covered entities to provide or cover abortion services. The Rule specifically incorporates the federal statutory protections for religious and conscience-based objections described above, 45 C.F.R. § 92.2(b)(2), and it does not displace the “provisions in the ACA related to abortion services,” *see* 81 Fed. Reg. at 31,379 & n.14, including the provision that “[n]othing in [the ACA] shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage[] [or] funding[] . . . [of] abortions,” 42 U.S.C. § 18023(c)(1).

1. Nondiscrimination on the basis of sex in the provision of health care services

In keeping with Section 1557 itself, *see* 42 U.S.C. § 18116(a), the Rule ensures that “an individual shall not, on the basis of . . . sex, . . . be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which [the Rule] applies,” 45 C.F.R. § 92.101(a). As noted, the Rule neither requires any provider to perform any particular service nor prevents medical professionals from exercising and expressing their medical judgments in a nondiscriminatory manner. *See, e.g.*, 81 Fed. Reg. at 31,377 (noting that the Rule does not “state that certain practices as a matter of law are ‘always’ or ‘never’ permissible” because “[t]he determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent”).⁵ Indeed, the Rule does not require health care providers “to fundamentally change the nature of their operations.” 81 Fed. Reg. at 31,455. Rather, the Rule simply prevents providers from “deny[ing] or limit[ing] services based

⁵ No Plaintiff alleges the intent to deny medical services other than those relating to gender transition or termination of pregnancy—services such as treatment for cancer or for a broken bone, for example—to anyone on account of their “gender identity” or based on them having received services for “termination of pregnancy” in the past. 45 C.F.R. § 92.4; *see id.* § 92.101. Nor do the State Plaintiffs allege the intent to prohibit all medical services for gender transition from being performed at state-run health care facilities. *Cf.* Franciscan Br. 11-12; States Br. 23-24.

on an individual's sex, without a legitimate nondiscriminatory reason.” *Id.* If a provider establishes that his or her treatment decisions were driven by such a reason—for example, by the nondiscriminatory application of his or her “[s]cientific or medical” judgment to the situation at hand, *id.* at 31,405—there is no violation. The Department has committed that it “*will not second-guess* a covered-entity’s neutral nondiscriminatory application of evidence-based criteria used to make medical necessity . . . determinations.” *Id.* at 31,436-37 (emphasis added). Likewise, the Rule will not be violated where one of the “Federal statutory protections for religious freedom and conscience” discussed above applies. 45 C.F.R. § 92.2(b)(2).

2. Nondiscrimination on the basis of sex in the provision of health insurance coverage

The Rule prohibits specified covered entities, *see id.* § 92.208, from “discriminat[ing] on the basis of . . . sex” in the provision or administration of “health-related insurance or other health-related coverage,” *id.* § 92.207(a).⁶ As the Department has repeatedly explained, the Rule “‘does not require [health insurance] plans to cover any particular benefit or service’”; rather, it prohibits “‘a covered entity [from having] a coverage policy that operates in a discriminatory manner.’” 81 Fed. Reg. at 31,434 (quoting 80 Fed. Reg. at 54,189). No part of the Rule is “intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.” 45 C.F.R.

⁶ With regard to timing, the Rule states that to the extent it “require[s] changes to health insurance or group health plan benefit design,” it becomes effective as to such plans on “the first day of the first plan year . . . beginning on or after January 1, 2017.” 81 Fed. Reg. 31,376. As to the Rule’s scope, there is no basis for the State Plaintiffs’ claim that the Rule requires changes to such plans offered to “*all* state employees.” *E.g.*, States Br. 24 (emphasis added). The Rule’s applicability is precisely tailored, *see* 45 C.F.R. § 92.208, and the Department explained in particular that, for example, “when a State receives Federal financial assistance for its Medicaid program, the State will be governed by Section 1557 in the provision of employee health benefits for its Medicaid employees, but not for its transportation department employees, assuming no part of the State transportation department operates a health program or activity.” *See* 81 Fed. Reg. at 31,437.

§ 92.207(d). Again, the Department “will not second-guess a covered-entity’s neutral nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations.” 81 Fed. Reg. at 31,436-37. Rather, a covered entity must simply “use a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.” *Id.*

As such, the Rule prohibits a covered entity from, among other things: denying, cancelling, limiting, or refusing to issue a health-related insurance plan, or denying or limiting coverage of a claim, or imposing additional cost sharing or restrictions on coverage on the basis of race, color, national origin, sex, age, or disability, *id.* § 92.207(b)(1); and using marketing practices or benefit designs that discriminate on those grounds, *id.* § 92.207(b)(2). When considering allegations that a covered entity has violated these prohibitions, the Department will “apply basic nondiscrimination principles in evaluating whether a covered entity’s [action] . . . is the product of discrimination.” 81 Fed. Reg. at 31,429.

Absent an applicable religious defense, *see* 45 C.F.R. § 92.2(b)(2), the Rule does prohibit covered entities’ health insurance plans from categorically excluding or limiting coverage for “*all* health services related to gender transition,” *id.* § 92.207(b)(4) (emphasis added). The Department explained that this particular section of the Rule aims to correct the fact that “in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals.” 81 Fed. Reg. at 31,429. Though “[h]istorically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental[,], . . . such across-the-board categorization is now recognized as outdated and not based on current standards of care.” *Id.* (footnotes omitted); *accord id.* at 31,435; *see* 80 Fed. Reg. at 54,189 (NPRM) (similar).

Significantly, and contrary to Plaintiffs’ repeated allegations, *e.g.*, Franciscan Br. 33-35, 37, 40-42; States Br. 22, by acknowledging that a health insurance policy’s blanket characterization of all transition-related treatment “as cosmetic or experimental” is “not based on current standards of care,” 81 Fed. Reg. at 31,429, the Department did not purport to establish a national standard of care in this field or regulate what medical advice doctors and other health care professionals can provide. To the contrary, the Department specifically “recognize[d] that . . . standards of medical care” “related to gender transition . . . continue to evolve,” *id.* at 31,435, and the Rule expressly disclaims any application that would “determine, or restrict a covered entity from determining, whether a particular health service is medically necessary,” 45 C.F.R. § 92.207(d).

Moreover, the Rule does not “compel insurance coverage for medical transitions,” *e.g.*, Franciscan Br. 29, or for any other medical services for that matter; instead, the Rule prohibits policies from operating in a discriminatory manner, both in design and implementation. Precluding a categorical exclusion for “all health services related to gender transition,” 45 C.F.R. § 92.207(b)(4), simply means that a covered policy may not automatically deny or limit claims for *all* such services across the board.⁷ And the Department has made clear that it “will evaluate whether a particular exclusion is discriminatory based on the application of longstanding nondiscrimination principles to the facts of the particular plan or coverage.” 81 Fed. Reg. at

⁷ Plaintiffs’ focus on TRICARE, the military’s insurance program, and Medicare, Franciscan Br. 27-30, is misplaced. TRICARE’s exclusion for “[a]ll services and supplies directly and or indirectly related to surgical treatment for gender dysphoria,” TRICARE Policy Manual 6010.57-M, Ch. 7, § 1.2 at 4.1, does not address other types of treatment for gender dysphoria, “such as hormone therapy and psychotherapy,” 81 Fed. Reg. at 31,435-36. The same goes for Medicare, which, as Plaintiffs themselves acknowledge, simply does not “require coverage for gender reassignment surgery” for Medicare recipients and instead permits “states and local administrators to make coverage determinations on a case-by-case basis,” Franciscan Br. 27; *see* Pls.’ App’x 733.

31,435. Of Plaintiffs here, only Franciscan Alliance alleges that it is providing its employees with health insurance that categorically excludes all gender transition services, but Franciscan Alliance also alleges that its sincere religious beliefs require such an exclusion. Franciscan Br. 11. The Rule contemplates addressing such religious objections. *See* 45 C.F.R. § 92.2(b)(2). Notably, none of the State Plaintiffs allege that their employee health benefit plans contain a similar categorical exclusion for all transition-related services. The State Plaintiffs’ claims premised on the incorrect assertion that the Rule “compels the States to provide insurance coverage for medical transition procedures,” Franciscan Br. 11-12; *accord* States Br. 24, can go no further.

In sum, just as the Rule does not mandate that any specific services be covered generally, it likewise neither “affirmatively require[s] covered entities to cover any . . . procedure or treatment for transition-related care” in particular, nor “preclude[s] a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.” 81 Fed. Reg. at 31,429; *see* 45 C.F.R. § 92.207(b)(5) (preventing covered entities from denying or limiting coverage, or imposing additional cost sharing or other restrictions on coverage, for specific health services related to gender transition only “if such denial, limitation, or restriction results in discrimination against a transgender individual”). The Rule does not prevent covered entities from making nondiscriminatory choices with regard to coverage for transition-related services or any other medical services.

D. Administrative And Judicial Enforcement Mechanisms Under Section 1557

Congress has prescribed a detailed scheme of administrative and judicial review of alleged violations of Section 1557. HHS regulations and other policies, in turn, govern the agency’s own investigation and enforcement proceedings.

Section 1557 specifies that the “enforcement mechanisms provided for and available under [Title VI, Title IX, Section 504, or the Age Act] shall apply for purposes of violations of” Section

1557. 42 U.S.C. § 18116(a). In each of these statutes, Congress has set forth detailed procedures, based on those first introduced in Title VI in 1964, *see id.* §§ 2000d-1, 20003-2, for administrative and judicial review of a governmental finding of discrimination and decision to withdraw federal financial assistance, *accord* 20 U.S.C. §§ 1682, 1683 (Title IX); 42 U.S.C. §§ 6104, 6105 (Age Act); 29 U.S.C. § 794a(a)(2) (Section 504) (cross-referencing “[t]he remedies, procedures, and rights set forth in [T]itle VI”).⁸ The Rule likewise specifies that the procedures set forth in the Department’s Title VI regulations govern proceedings concerning discrimination on the basis of race, color, national origin, sex, and disability under Section 1557. 45 C.F.R. § 92.302(a) (citing 45 C.F.R. §§ 80.6-11).

Section 1557 investigations are conducted by HHS’s Office for Civil Rights.⁹ In keeping with Congress’s instructions, OCR’s goal at every step is to help covered entities achieve “compliance . . . by voluntary means” wherever possible. 42 U.S.C. § 2000d-1; *see, e.g.*, 45 C.F.R. §§ 80.6(a), 80.7(d)(1), 80.8(a), 80.8(d). Indeed, although as of September 2015 OCR was receiving approximately 3,000 civil rights complaints annually, 80 Fed. Reg. at 54,207, in the past

⁸ In the Rule’s preamble, the Department also stated that, “based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance.” 81 Fed. Reg. at 31,439; *see* 45 C.F.R. § 92.302(d). Of course, any lawsuit brought by a private litigant under Section 1557 would inherently provide the opportunity for judicial review of the very types of arguments that Plaintiffs attempt to raise here (*e.g.*, that their health care practices and policies are nondiscriminatory or that certain of the Rule’s built-in protections for state laws and religious and conscience-based objections apply).

⁹ *See Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services*, 45 Fed. Reg. 47,474, 47,479 (July 15, 1980) (delegating the Secretary’s authority under Title VI, Title IX, the Age Act, and Section 504, *inter alia*, to OCR); *see, e.g.*, 45 C.F.R. § 92.302(c) (referencing OCR’s authority to “initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law”).

fifteen years, only one of OCR's civil rights enforcement actions required resolution, as a last resort, through the termination of federal financial assistance by the Department.

An OCR investigation of a potential Section 1557 violation may be instituted after an OCR compliance review, 45 C.F.R. § 80.7(a), or after OCR receives a complaint asserting potential discrimination, *id.* § 80.7(b). OCR investigations "include, where appropriate, a review of the pertinent practices and policies of the [covered entity], the circumstances under which the possible noncompliance . . . occurred, and other factors relevant to a determination as to whether the" covered entity failed to comply with Section 1557. 45 C.F.R. § 80.7(c). In conducting its investigations, OCR gathers relevant facts through document requests, interviews, and on-site visits.

If OCR determines, after review of a complaint and any subsequent investigation, that further action is not warranted, OCR will inform both the covered entity and any complainant. *Id.* § 80.7(d)(2). If, on the other hand, an investigation indicates a Section 1557 violation, OCR must inform the covered entity and attempt to resolve the matter "by informal means whenever possible." 45 C.F.R. § 80.7(d)(1). If OCR "determine[s] that compliance cannot be secured by voluntary means," 42 U.S.C. § 2000d-1, HHS can either refer the matter to the Department of Justice with a recommendation that appropriate judicial proceedings be brought, *see id.*; 45 C.F.R. § 80.8(a), or HHS can institute administrative proceedings to determine whether to terminate the covered entity's Departmental funding, 42 U.S.C. § 2000d-1; 45 C.F.R. § 80.8(c); *see* 81 Fed. Reg. at 31,439. Such proceedings begin with notice to the covered entity of the relevant charges and the proposed enforcement action, 45 C.F.R. § 80.9(a), and also provide the covered entity "opportunity for hearing," 42 U.S.C. § 2000d-1; *see* 45 C.F.R. § 80.9(a). Hearings are conducted in accordance with the Administrative Procedure Act ("APA"). *See* 45 C.F.R. § 80.9. At the

conclusion of a hearing, the hearing officer—an administrative law judge—issues either an initial or recommended decision that is subject to review by the Department’s Civil Rights Reviewing Authority. *See id.* § 80.10(a). Further review—by the Secretary—may also be sought. *See id.* § 80.10(e).

Any final decision terminating federal financial assistance under Section 1557 must include “an express finding on the record . . . of a failure to comply with [a] requirement” under that provision. 42 U.S.C. § 2000d-1. Congress has also provided that “such termination . . . shall be limited to the particular political entity, or part thereof, or other recipient as to whom such a finding has been made and, shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.” *Id.* In addition, any termination of federal financial assistance cannot be made effective until thirty days after the Department files “a full written report of the circumstances and the grounds” for the termination “with the committees of the House and Senate having legislative jurisdiction over the program or activity involved.” *Id.*

Finally, in addition to prescribing the administrative proceedings described above, *see id.*, Congress has ensured the opportunity for judicial review of any final decision by the Department terminating federal financial assistance on the basis of noncompliance with Section 1557, *see id.* § 2000d-2. Specifically, judicial review may be had either (1) “as may otherwise be provided by law for similar action taken by [the Department] on other grounds”—*i.e.*, as set forth in the statutory scheme governing the particular federal financial assistance at issue, *id.*; *see, e.g., id.* § 1395cc(h)(1)(A) (providing for judicial review of an HHS decision terminating certain Medicare funding); *id.* § 1316(e)(2)(C) (same, Medicaid); or (2) in the event any such statutory scheme does not itself provide for judicial review, such review is available under the APA, *id.* § 2000d-2; *see, e.g., 5 U.S.C. §§ 702, 704.* Accordingly, in the unlikely event of a Departmental decision

withdrawing any federal financial assistance on the basis of a violation of Section 1557, Plaintiffs could pursue their claims in court at that point.

II. Procedural Background

Plaintiffs filed this lawsuit on August 23, 2016. *See* Compl. Plaintiffs consist of eight “State Plaintiffs”: Arizona, Kansas, Kentucky, Louisiana, Mississippi, Nebraska, Texas, and Wisconsin, *see* First Am. Compl. ¶¶ 1-4; and the “Non-State Plaintiffs,” which assert religious objections to certain of the Rule’s alleged requirements: Franciscan Alliance, a Roman Catholic nonprofit hospital system, *id.* ¶ 6; Specialty Physicians, a physicians’ practice managed by Franciscan, *id.* ¶ 9; and the Christian Medical & Dental Associations (“CMDA”), a membership association suing on behalf of its 18,000 members, *id.* ¶¶ 5, 71. On October 21, 2016, Plaintiffs filed motions seeking partial summary judgment or, in the alternative, a preliminary injunction, by January 1, 2017. ECF Nos. 22, 24. By Order dated November 1, 2016, the Court stayed summary judgment proceedings and set a schedule for briefing Plaintiffs’ request for a preliminary injunction only. ECF No. 32.

STANDARD OF REVIEW

“A preliminary injunction is an extraordinary remedy that should not be granted unless” the plaintiff shows “a substantial threat” of irreparable injury, “a substantial likelihood” of success on the merits, that the “threatened injury” to the plaintiff “outweighs the threatened harm” to the defendant, and that “granting the preliminary injunction will not disserve the public interest.” *Google, Inc. v. Hood*, 822 F.3d 212, 220 (5th Cir. 2016) (citation omitted). Relief “should only be granted when the movant has clearly carried the burden of persuasion” on all four requirements. *Anderson v. Jackson*, 556 F.3d 351, 360 (5th Cir. 2009). “The Fifth Circuit frequently cautions that . . . ‘the decision to grant a preliminary injunction is to be treated as the exception rather than the rule.’” *Matrix Partners VIII v. Natural Res. Recovery*, No. 08-cv-547, 2009 WL 175132, at

*6 (E.D. Tex. Jan. 23, 2009) (alteration omitted) (quoting *House the Homeless, Inc. v. Widnall*, 94 F.3d 176, 180 (5th Cir. 1996)).

ARGUMENT

I. PLAINTIFFS CANNOT ESTABLISH IRREPARABLE INJURY

The Supreme Court has made clear that a preliminary injunction cannot be entered based on a mere “possibility” of irreparable harm; rather, a plaintiff must “demonstrate that irreparable injury is *likely* in the absence of an injunction.” *Winter*, 555 U.S. at 22. The threat of irreparable injury must be “real,” “substantial,” and “immediate.” *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983).

Plaintiffs’ alleged injuries are none of these things. The crux of Plaintiffs’ theory of irreparable injury is that, under the Rule, and at pain of hypothetically losing their Departmental funding, the Non-State Plaintiffs will “be forced to provide” medical services, and health insurance coverage for services, “that violate[] their medical and religious judgment,” Pls.’ Supp. Br. 1, and that the State Plaintiffs will be “disable[d] . . . from following their own healthcare laws and policies,” *id.* at 2. In fact, the Rule states the opposite. Under the Rule, “[s]cientific or medical reasons can justify distinctions based on” sex. 81 Fed. Reg. at 31,405. Like “Texas law,” the Rule “zealously protects the physician-patient relationship and the independent medical judgment of doctors.” Pls.’ Supp. Br. 2. The Rule also expressly protects “religious freedom and conscience”: no part of it can be applied so as to violate RFRA or the Weldon, Church, and Coats amendments. 45 C.F.R. § 92.2(b)(2). Nor can any part of the Rule be applied in contravention of state laws “regarding the prohibition of . . . coverage[] [or] funding . . . [of] abortions. 42 U.S.C. § 18023(c); *see* 81 Fed. Reg. at 31,379 & n.14. Plaintiffs are conspicuously silent when it comes to these built-in protections. Their silence is telling. Particularly once those protections are considered—which,

under the Rule, they must be, *see* 45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379—it becomes clear that the injuries Plaintiffs allege are not “likely,” *Winter*, 555 U.S. at 22 (emphasis omitted).

For example, Plaintiffs argue at length that the Rule violates the Religious Freedom Restoration Act, *Franciscan Br.* 23-32, but their argument makes no sense given that the Rule explicitly disavows any potential application that would violate RFRA. Plaintiffs’ allegations about the Rule’s purported requirements concerning abortion are likewise unfounded. As noted above, the Rule does not state that it requires covered entities to provide or cover abortion services, it incorporates federal statutory protections for religious freedom and conscience, and it does not “preempt or otherwise have any effect on” the State Plaintiffs’ “laws regarding the prohibition of . . . coverage[] [or] funding . . . [of] abortions.” 42 U.S.C. § 18023(c).¹⁰ In light of these facts, Plaintiffs have failed to credibly explain how the Rule “pressures” them, *e.g.*, *Franciscan Br.* 7, 10, 45, much less requires them, to change their health care practices and health insurance policies

¹⁰ Even a cursory search reveals that the State Plaintiffs have laws that forbid comprehensive health insurance plans from covering abortions and/or prevent state funds or facilities from being used for abortions—state laws that the Rule does not displace. 42 U.S.C. § 18023(c); *see, e.g.*, *Ariz. Rev. Stat. Ann.* § 35-196.02(B) (prohibiting public money from being “expended directly or indirectly to pay . . . [for] coverage, benefits or services related to the performance of any abortion”); *Kan. Stat. Ann.* § 40-2,190(a) (“Any individual or group health insurance policy . . . shall exclude coverage for elective abortions”); *Ky. Rev. Stat. Ann.* § 304.5-160(1) (“No health insurance contracts, plans or policies delivered or issued for delivery in the state shall provide coverage for elective abortions”); *La. Stat. Ann.* § 40:1061.6 (“Notwithstanding any other provision of law to the contrary, no public funds[] made available to any [state agency] . . . shall be used in any way for, to assist in, or to provide facilities for an abortion, except when the abortion is medically necessary to prevent the death of the mother.”); *Miss. Code Ann.* § 41-41-91 (“[N]o public funds . . . shall be used in any way for, to assist in, or to provide facilities for abortion.”); *Neb. Rev. Stat. Ann.* § 44-8403(2) (“No health insurance plan, contract, or policy delivered or issued for delivery in the State of Nebraska shall provide coverage for an elective abortion”); *Tex. Health & Safety Code Ann.* § 32.005 (“Notwithstanding any other provision of this chapter, funds administered under this chapter may not be used to provide abortion services unless the mother’s life is in danger.”); *Wis. Stat. Ann.* § 20.927 (“no funds of this state . . . or of any subdivision or agency of this state . . . and no federal funds passing through the state treasury shall be authorized for or paid to a physician or surgeon or a hospital, clinic or other medical facility for the performance of an abortion”).

concerning abortion. Far from “real,” “substantial,” and “immediate,” *Lyons*, 461 U.S. at 111, the injuries that Plaintiffs allege from the Rule’s prohibition of discrimination on the basis of termination of pregnancy are unfounded.

Plaintiffs also purport to identify the Rule’s “consequences” by mischaracterizing parts of the Rule’s preamble as “requirements.” *E.g.*, Franciscan Br. 6-8. At root, Plaintiffs’ error lies in viewing the Rule as imposing specific demands, when in fact it requires covered entities only to provide health care and health insurance in a nondiscriminatory manner. *See, e.g.*, 81 Fed. Reg. at 31,429, 31,455. The Department’s approach in the Rule embodies bedrock principles of antidiscrimination law. If, for example, a patient alleges that a provider treated him or her differently on a ground prohibited under the Rule, the provider can advance a legitimate, nondiscriminatory reason for the provider’s actions—*e.g.*, medical judgment—which will be considered, along with any statutory protections, before it is determined whether Section 1557 has been violated. *See generally McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802-03 (1973). Time and again in the rulemaking, therefore, in any number of different contexts, the Department emphasized that it will “evaluate[] each situation on a case-by-case basis.” 81 Fed. Reg. at 31,393; *accord id.* at 31,419, 31,432, 31,440; 80 Fed. Reg. at 54,185. In the face of these commitments, Plaintiffs’ alleged injuries can only be speculative and conjectural.

Moreover, the Rule patently does not prevent employers from providing their employees with reasonable religious accommodations. *See* Pls.’ Supp. Br. 3-4. As Plaintiffs acknowledge, “providing [such] accommodations is not difficult, particularly when other doctors are available to perform the requested procedures.” Franciscan Br. 22. Likewise, providing such accommodations—by excusing an objecting provider and allowing a non-objecting provider to perform a particular service—does not violate the Rule. Contrary to Plaintiffs’ allegations, nothing

in the Rule requires hospitals to “force their doctors and nurses” who object on religious or conscience-based grounds “to participate in [gender transition] procedures,” or any other medical procedures for that matter. *Id.* at 23. To the contrary, the Rule expressly incorporates protections for providers’ religious freedom and conscience. 45 C.F.R. § 92.2(b)(2).

Finally, even if the Rule operated as Plaintiffs allege—which it does not—Plaintiffs’ claimed injuries still would be speculative. Plaintiffs have not identified any enforcement action against them under the Rule, whether by HHS or a private litigant, where a finding of unlawful discrimination and a termination of funding or a damages award are imminent. Even were such an action foreseeable, it could have no concrete effects until the conclusion of the extensive administrative and/or judicial procedures described above and addressed further below. *See Google*, 822 F.3d at 227 (vacating a preliminary injunction that “covers a fuzzily defined range of enforcement actions that do not appear imminent”). Here, as in *Lyons*, “[t]he speculative nature of [Plaintiffs’] claim of future injury requires a finding that this prerequisite of equitable relief has not been fulfilled.” 461 U.S. at 111; *see, e.g., Mannatech, Inc. v. Wellness Quest, LLC*, No. 3:14-cv-2497, 2014 WL 11515729, at *1 (N.D. Tex. Nov. 4, 2014) (“The threat of irreparable injury is perhaps the single most important prerequisite for the issuance of a preliminary injunction.” (citation omitted)); *accord Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1260 (10th Cir. 2004).

II. PLAINTIFFS ARE UNLIKELY TO SUCCEED BECAUSE THE COURT LACKS JURISDICTION

Plaintiffs’ attempt to mount a pre-enforcement challenge to the Rule fails. Any allegation that any of the Plaintiffs are now, or imminently will be, subject to a finding of unlawful discrimination under the Rule is speculative. Thus, although “in some cases, pre-enforcement review is acceptable,” *Tex. Indep. Producers & Royalty Owners Ass’n v. EPA*, 413 F.3d 479, 482

(5th Cir. 2005), it is not acceptable here. To start, “pre-enforcement review is still subject to the constraints of the ripeness test,” *id.*, and Plaintiffs’ claims are not ripe. *See infra* Section II.A. All Plaintiffs lack standing for similar reasons, and CMDA lacks standing for additional reasons as well. *See infra* Section II.B. Finally, even if Plaintiffs’ claims were ripe and Plaintiffs had standing, Section 1557 “specifically demonstrates that Congress has prohibited pre-enforcement review,” *Tex. Indep. Producers & Royalty Owners Ass’n*, 413 F.3d at 482, by requiring Plaintiffs to press their claims before HHS in any enforcement action the Department might instigate to determine, in fact- and case-specific fashion, whether Plaintiffs have violated Section 1557, with judicial review then available thereafter. *See infra* Section II.C.

A. Plaintiffs’ Claims Are Not Ripe

Because Plaintiffs’ alleged injuries are “speculative and may never occur,” their lawsuit is not ripe, and therefore is not “appropriate for judicial review.” *United Transp. Union v. Foster*, 205 F.3d 851, 857 (5th Cir. 2000); *see Texas v. United States*, 523 U.S. 296, 300 (1998) (a plaintiff’s claim “is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all”). The ripeness requirement is designed “to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Ohio Forestry Ass’n, Inc. v. Sierra Club*, 523 U.S. 726, 732-33 (1998) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). “[I]n the context of rulemaking,” therefore, courts typically “wait until a rule has been applied before granting review.” *Cent. & Sw. Servs., Inc. v. EPA*, 220 F.3d 683, 690 (5th Cir. 2000) (citation omitted).

Plaintiffs’ overbroad and incorrect assertions about what the Rule requires underscore the absence of a sufficiently concrete allegation of injury. Rather than challenging the application of

the Rule in a particular instance, Plaintiffs seek to challenge aspects of the Rule in the abstract. Judicial review must “wait until” the Rule “has been applied” and a finding of unlawful discrimination has been made. *Id.* “That the issues here would be significantly aided ‘by further factual development’ is an understatement.” *Texas v. EEOC*, 827 F.3d 372, 392 (2016) (Higginbotham, J., dissenting) (quoting *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2347 (2014)), *pet. for reh’g granted*, 838 F.3d 511 (5th Cir. 2016) (per curiam).¹¹

Plaintiffs’ focus on examples and guidance provided in the Rule’s preamble—the purpose of which is to assist covered entities in understanding their obligations under the Rule’s nondiscrimination provisions, now separately codified at 45 C.F.R. pt. 92—is particularly misplaced. The D.C. Circuit rejected similar challenges as unripe in *Natural Resources Defense Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). There, as here, the agency committed to “evaluat[ing] [matters] on a case-to-case basis,” such that the plaintiffs could “not demonstrate[] that any of the” examples given in the preamble “ha[d] immediate legal or practical consequences.” *Id.* Here, too, “[h]ow [the Department] will use or rely on or interpret what it said in the preamble is uncertain,” and there is no “significant hardship to the parties from waiting for a real case to emerge.” *Id.* That is especially true because Section 1557 “provides for judicial review of any [HHS] decision” to terminate federal financial assistance. *Id.*; see 42 U.S.C. § 2000d-2.

¹¹ In *Texas*, No. 7:16-cv-54, this Court found that the plaintiffs’ challenge to certain guidance documents interpreting Title IX was ripe because the question at issue there was “purely legal” and “Defendants asserted . . . that Plaintiffs are not in compliance with their obligations under Title IX given their refusal to change their policies.” 2016 WL 4426495, at *7. While Defendants respectfully disagree with the Court’s decision in *Texas*, the Court’s reasoning there does not apply here, where the parties’ dispute involves myriad facts that cannot be determined outside the context of a particular enforcement action, and where Defendants have demonstrated that the challenged regulation does not require what Plaintiffs claim it does.

Ultimately, Plaintiffs’ speculation regarding the potential for a finding of unlawful discrimination by the Department and the loss of federal financial assistance “rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas*, 523 U.S. at 300. Plaintiffs’ concern about the possibility of private lawsuits against them under Section 1557 does not change the analysis. Plaintiffs have not alleged that any such lawsuits have materialized in the six years since Section 1557 has been on the books, and even were such lawsuits to be filed in the future, courts could judge at that point—on the basis of concrete facts, and upon considering Plaintiffs’ defenses—whether any violations of Section 1557 had in fact occurred. At this stage, no case or controversy exists to justify this Court’s intervention.

B. Plaintiffs Lack Standing

For similar reasons, Plaintiffs lack standing. The “irreducible constitutional minimum of standing contains three elements.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). The plaintiff must have: (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Id.* “The party invoking federal jurisdiction bears the burden of establishing these elements,” *id.* at 561, as to “each claim he seeks to press,” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006); *see Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998) (“Without jurisdiction the court cannot proceed at all in any cause.” (citation omitted)).

1. All Plaintiffs lack standing

As detailed above, Plaintiffs’ claims are not ripe because the injuries they allege—a finding of unlawful discrimination and the termination of federal financial assistance at the conclusion of administrative proceedings, damages liability at the conclusion of private lawsuits—are speculative. The conjectural nature of Plaintiffs’ alleged injuries is confirmed by the fact that the Rule protects the nondiscriminatory expression and application of medical judgment, it

incorporates existing federal statutory protections for religious and conscience-based objections, it does not displace ACA provisions concerning abortion, and indeed it does not require Plaintiffs to perform or cover any particular medical services but rather ensures that services are offered and covered in manners free from discrimination. Thus, because Plaintiffs’ alleged injuries are not “actual or imminent,” but rather are “conjectural” and “hypothetical,” all Plaintiffs lack standing. *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan*, 504 U.S. at 560).

2. CMDA lacks associational standing

In addition, CMDA purports to sue on behalf of its nearly 18,000 members, *e.g.*, First Am. Compl. ¶¶ 5, 71; Franciscan Br. 9-10, but it lacks standing to do so.¹² “[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977). CMDA fails the first prong to the extent its claims concern the provision of medical services, and it fails the third prong with regard to its claim pursuant to the Religious Freedom Restoration Act.

First, the injuries CMDA alleges concerning the Rule’s effects on its members’ provision of medical services all hinge on its members’ religious or conscience-based objections to performing certain such services. *E.g.*, Franciscan Br. 9-11, 22, 24-25; First Am. Compl. ¶¶ 79, 81, 83, 323-24. But consistent with the Church Amendment—which the Rule specifically

¹² In their complaint (but not in their briefs) Plaintiffs state that CMDA also purports to sue on its own behalf, *e.g.*, First Am. Compl. ¶ 5, but its allegations are insufficient in this regard. CMDA has not alleged that it is a covered entity under the Rule, *e.g.*, that it receives “Federal financial assistance provided or made available by the Department” to carry out a “health program or activity.” *See* 45 C.F.R. § 92.2(a).

incorporates, *see* 45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379 & n.12—the Rule cannot be applied so as to “require[]” an “individual . . . to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions,” 42 U.S.C. § 300a-7(d). Accordingly, no CMDA member has established any actual or imminent injuries from the Rule’s effects on their provision of health care services. Because no CMDA member has standing to challenge the Rule in this regard, *see Spokeo*, 136 S. Ct. at 1548, neither does CMDA, *see Hunt*, 432 U.S. at 343.

In addition, CMDA’s claim under the Religious Freedom Restoration Act, *see Franciscan Br. 23-32*, “requires the participation of individual members.” *Hunt*, 432 U.S. at 343. Determining whether CMDA’s members are entitled to relief under RFRA would require the Court to identify the precise contours of a particular sincere religious belief, determine whether the Rule’s particular application substantially burdens the exercise of that belief, *see* 42 U.S.C. § 2000bb-1(a), and, if so, decide whether the Rule’s application “is in furtherance of a compelling governmental interest[] and . . . is the least restrictive means of furthering that . . . interest,” *id.* § 2000bb-1(b). Clearly, each of these inquiries would turn on factors specific not only to a particular circumstance, but also to a particular CMDA member and his or her unique religious views and practices.¹³

¹³ Notably (and understandably), Plaintiffs do not assert that all 18,000 CMDA members share the same religious beliefs, health care practices, and health insurance policy exclusions. To the contrary, Plaintiffs quite carefully refrain from doing so, making allegations about how “[m]any”—not all—“of CMDA’s members will be impacted by [the] Rule.” First Am. Compl. ¶ 78; *accord id.* ¶¶ 79, 80, 83, 84. The statement of faith that a health care professional must sign in order to join CMDA, *see* Pls.’ App’x 20 (citing CMDA, Our Mission & Values, <https://cmda.org/about/page/our-mission-vision>), begins with a parenthetical acknowledging the diversity of members’ religious outlooks, and the statement itself does not touch on any of the specific religious views that plaintiffs ascribe to all CMDA members by virtue of ethics statements adopted by the organization’s leadership, *Franciscan Br. 9*; Pls.’ App’x 20, 22. Moreover, while

The Supreme Court rejected a claim to associational standing like CMDA's in *Harris v. McRae* because "it is necessary in a free exercise case for one to show the coercive effect of [the challenged law] *as it operates against him* in the practice of his religion." 448 U.S. 297, 321 (1980) (emphasis added); see *Cornerstone Christian Sch. v. Univ. Interscholastic League*, 563 F.3d 127, 134-35 (5th Cir. 2009) (applying *McRae* and rejecting similar claim to associational standing); *Soc'y of Separationists, Inc. v. Herman*, 959 F.2d 1283, 1288 (5th Cir. 1992) (en banc) (same). As was true of the free exercise claim in *McRae*, the RFRA "claim asserted here is one that ordinarily requires individual participation," not least because CMDA itself admits a "diversity of view within [its] membership." 448 U.S. at 321; see *Soc'y of Separationists*, 959 F.2d at 1288 ("It is often difficult for religious organizations to assert free exercise claims on behalf of their members because the religious beliefs and practices of the membership differ." (citing *McRae*, 448 U.S. 297)). Accordingly, this Court cannot "resol[ve] . . . the individualized element of coercion" that lies at the heart of CMDA's claim under RFRA. *Cornerstone Christian Sch.*, 563 F.3d at 134. "It is thus clear that the participation of [CMDA's] individual members . . . is essential to a proper understanding and resolution of their" RFRA claim, such that CMDA lacks standing to bring that claim on its members' behalf. *McRae*, 448 U.S. at 321.

C. Section 1557 Requires Plaintiffs To Adhere To Its Specified Mechanisms For Administrative And Judicial Review

Plaintiffs' pre-enforcement challenge is not justiciable for another reason: Section 1557 "demonstrates that Congress has prohibited pre-enforcement review," *Tex. Indep. Producers & Royalty Owners Ass'n*, 413 F.3d at 482, by requiring exhaustion of administrative remedies and thereby delaying judicial review of Plaintiffs' claims. Any withdrawal of Plaintiffs' federal

those ethics statements may "reflect[]" or "explain[]" . . . the beliefs of [CMDA] members" generally, Pls.' App'x 20, they do not profess to speak for, much less bind, all CMDA members, and they are written in the voice of CMDA itself, not that of its membership, *e.g.*, *id.* at 28, 451.

financial assistance by the Department could only occur after the comprehensive proceedings described above. 42 U.S.C. § 18116(a); *e.g.*, *id.* § 2000d-1; *see* 45 C.F.R. §§ 92.301(a), 92.302. And Congress has ensured that any such determination would be subject to judicial review. *E.g.*, 42 U.S.C. § 2000d-2. By imposing these requirements and assurances, Congress has divested this Court of jurisdiction over Plaintiffs’ current (unexhausted) claims.

Congress commonly divests federal district courts of original federal question jurisdiction, *see* 28 U.S.C. § 1331, in two primary ways: “by imposing exhaustion requirements and by imposing channeling requirements,” *Harkness v. United States*, 727 F.3d 465, 469 (6th Cir. 2013). With respect to exhaustion, the Supreme Court “has acknowledged the general rule that parties exhaust prescribed administrative remedies before seeking relief from the federal courts.” *McCarthy v. Madigan*, 503 U.S. 140, 144-45 (1992). “If Congress itself imposes an exhaustion requirement, courts must enforce its express terms” and failure to exhaust deprives the court of jurisdiction. *FDIC v. Scott*, 125 F.3d 254, 257 (5th Cir. 1997) (citing *Coit Independence Joint Venture v. FSLIC*, 489 U.S. 561, 579 (1989)).

Channeling requirements are another way for Congress to “delay[] judicial review” by “allocat[ing] initial review to an administrative body,” *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994)—*i.e.*, to “remove certain claims from the general jurisdiction of the federal courts in order to channel [those] claims into a system of statutory review,” *Elgin v. Dep’t of Treasury*, 132 S. Ct. 2126, 2141 (2012). Where Congress creates a “special statutory review scheme . . . it is ordinarily supposed that Congress intended that procedure to be the exclusive means of obtaining judicial review in those cases to which it applies.” *Jarkesy v. SEC*, 803 F.3d 9, 15 (D.C. Cir. 2015) (citation omitted).

“In some cases, including this one, the distinction between” an exhaustion requirement and a channeling provision “is difficult to locate, and is perhaps even illusory,” because “the effect of a congressional command is the same—judicial review is precluded until the statutory conditions have been met.” *Harkness*, 727 F.3d at 469.¹⁴ As described above, Congress has set forth a comprehensive scheme of administrative and judicial review for alleged violations of Section 1557. But rather than raising their claims in the context of a specific enforcement action to challenge a particular allegation of unlawful discrimination, Plaintiffs have asked this Court for a blanket, pre-enforcement determination that their practices are not discriminatory. This they cannot do. Whether viewed as channeling disputes to the agency prior to allowing for judicial review, or instead as instituting an exhaustion requirement, the comprehensive scheme that must precede any decision by the Department to terminate federal financial assistance on the basis of a violation of Section 1557 makes clear that Congress intended to preclude this Court from considering Plaintiffs’ pre-enforcement claims.

That Congress, in Section 1557, opted to incorporate the “enforcement mechanisms provided for and available under . . . [T]itle VI,” 42 U.S.C. § 18116(a), illustrates this point. Many courts have held that Title VI enacts “a comprehensive plan of enforcement” that divests district courts of jurisdiction over pre-enforcement challenges like Plaintiffs’. *Taylor v. Cohen*, 405 F.2d

¹⁴ In either case, because review is merely delayed, and not foreclosed, any “presumption of reviewability for all agency actions,” *Texas*, No. 7:16-cv-54, 2016 WL 4426495, at *10, is not triggered here, *see Elgin*, 132 S. Ct. at 2132-33; *Thunder Basin*, 510 U.S. at 207 n.8; *see, e.g., Nat’l Cable Television Co-op., Inc. v. Lafayette City*, No. 10-cv-2254, 2010 WL 4868158, at *5 n.10 (D. Kan. Nov. 23, 2010); *Ariz. State Dep’t of Educ. v. U.S. Dep’t of Educ.*, No. 06-cv-1719, 2007 WL 433581, at *4 (D. Ariz. Feb. 6, 2007); *see also Bd. of Educ. of the Highland Local Sch. Dist. v. U.S. Dep’t of Educ.*, No. 2:16-cv-524, 2016 WL 5372349, at *6-9 & n.2 (S.D. Ohio Sept. 26, 2016) (concluding that jurisdiction was lacking over APA and constitutional challenges in light of Title IX’s exclusive remedial scheme).

277, 279 (4th Cir. 1968).¹⁵ Courts have likewise ruled that exhaustion is a prerequisite for judicial review under provisions of other statutory schemes that are incorporated by Section 1557. *E.g.*, 42 U.S.C. § 1395cc(h)(1)(A); *see, e.g., Trade Around World of PA v. Shalala*, 145 F. Supp. 2d 653, 657 (W.D. Pa. 2001) (ruling that plaintiff skilled nursing facilities were required to exhaust administrative remedies before suing to challenge termination of participation in Medicare and Medicaid programs); *see also Mich. Ass’n of Homes & Servs. for Aging, Inc. v. Shalala*, 127 F.3d 496, 497 (6th Cir. 1997) (explaining that § 1395cc(h)(1) incorporates by reference 42 U.S.C. §§ 405(g), (h), which also require administrative exhaustion).

The policy justifications underlying both the exhaustion and the channeling doctrines apply with particular force in this case. *See, e.g., McCarthy*, 503 U.S. at 145; *Elgin*, 132 S. Ct. at 2140. The administrative process under Section 1557 is designed to allow the Department to make case-by-case determinations as to whether impermissible discrimination has occurred and, in so doing, to adequately assess the myriad factual intricacies upon which discrimination allegations turn. In that way, ascertaining whether a covered entity has engaged in unlawful discrimination is the quintessential “exercise of the agency’s discretionary power,” such that requiring Plaintiffs to proceed through the administrative review scheme is particularly important. *See McCarthy*, 503 U.S. at 145. What is more, were an administrative action to be instituted against a covered entity, the entity would have the opportunity to demonstrate to the Department that its practices are not

¹⁵ *See, e.g., Bakersfield City Sch. Dist. of Kern Cty. v. Boyer*, 610 F.2d 621, 624 (9th Cir. 1979) (“Comprehensive procedural requirements must be met before Federal financial assistance can be terminated for noncompliance [under Title VI].”); *accord NAACP v. Wilmington Med. Ctr., Inc.*, 453 F. Supp. 330, 340 (D. Del. 1978); *Sch. Dist. of the City of Saginaw v. U.S. Dep’t of Health, Educ. & Welfare*, 431 F. Supp. 147, 152 (E.D. Mich. 1977).

discriminatory or that it is shielded by any number of statutory protections.¹⁶ Permitting any necessary review, investigation, and ensuing administrative proceedings to take their course before judicial review “recognizes the notion, grounded in deference to Congress’ delegation of authority to coordinate branches of Government, that agencies, not the courts, ought to have primary responsibility for the programs that Congress has charged them to consider,” and would allow the Department to “apply its special expertise.” *Id.*; *see also Elgin*, 132 S. Ct. at 2140 (delaying judicial review might have the benefit of “obviat[ing] the need” for court intervention). It is not surprising, therefore, that exhaustion requirements are quite common for discrimination claims. *See, e.g., Pacheco v. Mineta*, 448 F.3d 783, 788-89 (5th Cir. 2006); *Barnes v. Levitt*, 118 F.3d 404, 409 (5th Cir. 1997); *Francis v. Brown*, 58 F.3d 191, 193 (5th Cir. 1995). The Court should conclude that Congress intended to impose such a requirement here.

¹⁶ Likewise, as noted above, if a private litigant were to sue any of the Plaintiffs claiming a violation of Section 1557, Plaintiffs would “retain[] the ability, of course, to raise as a defense to [that] claim [the] arguments” that they attempt to present here. *Highland*, 2016 WL 5372349, at *8. One way or another, therefore, Plaintiffs will have a meaningful opportunity for judicial review if they are faced with a claim that their actions violate Section 1557.

III. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS

For all the reasons set forth above, Plaintiffs are unlikely to succeed because this Court lacks jurisdiction. But even if this Court had jurisdiction, and even if Plaintiffs had demonstrated irreparable harm, the Court still should not issue a preliminary injunction because Plaintiffs are not likely to succeed on the merits of their claims.

A. Plaintiffs' Administrative Procedure Act Challenges To The Rule Are Not Likely To Succeed

1. The Rule's interpretation of Section 1557's prohibition of sex discrimination as encompassing discrimination based on gender identity should be upheld under *Chevron*

Plaintiffs' primary claim, whether stated under the Administrative Procedure Act, *see* Franciscan Br. 12-19, or put forward under the guise of the Constitution's Spending Clause and Tenth Amendment, *see id.* at 23, 32; States Br. 2-24, is that the Rule's interpretation of Section 1557 as prohibiting discrimination on the basis of gender identity is contrary to law. Plaintiffs are incorrect.

Section 1557 provides, in relevant part, that "[a]n individual shall not, on the ground prohibited under . . . [T]itle IX . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health care program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). The "ground prohibited under" Title IX, *id.*, refers to discrimination "on the basis of sex," 20 U.S.C. § 1681(a). Defendants acknowledge that this Court recently held that the phrase "on the basis of sex" in a Department of Education regulation implementing Title IX as to certain sex-segregated facilities refers solely to "the biological and anatomical difference between male and female students as determined at their birth," even though such an interpretation would treat a transgender person inconsistently with his or her gender identity. *Texas*, No. 7:16-cv-54, 2016 WL 4426495, at *14. Defendants respectfully disagree with that determination. This case, however, presents a different question. The Rule

interprets the prohibition against discrimination in Section 1557 of the Affordable Care Act, not that in Title IX, *see* 45 C.F.R. § 92.1, and the health care context differs from the education context in several ways meaningful to the analysis, *see, e.g.*, 81 Fed. Reg. at 31,380. In addition, unlike the agency guidance at issue in this Court’s *Texas* decision, HHS’s interpretation of Section 1557 in the Rule was the product of notice-and-comment rulemaking, *see* 42 U.S.C. § 18116(c) (authorizing the HHS Secretary to promulgate implementing regulations), and as Plaintiffs acknowledge, *see* Franciscan Br. 12, the familiar two-part *Chevron* framework applies. *See Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984).

In evaluating the Rule under this framework, the Court must first determine, at step one, “whether Congress has directly spoken to the question at issue.” *Zermeno v. Lynch*, 835 F.3d 514, 517 (5th Cir. 2016) (citation omitted). “If not, the court” must proceed to step two and “determine whether the agency’s answer is based on a permissible construction of the statute.” *Id.* (citations and alterations omitted). The Rule passes that test.

a. Plaintiffs’ narrow interpretation of discrimination on the basis of sex is not compelled by the statutory text

Defendants agree with Plaintiffs that the statutory text should be the Court’s starting point at *Chevron* step one. *See* Franciscan Br. 13-14. But Section 1557 does not define discrimination “on the basis of sex,” and neither does Title IX. Nor does either statute address how to determine an individual’s sex in the event of a conflict between genetic or anatomical makeup and gender identity, or in the event that different indicators point in different directions. Plaintiffs insist that the term “sex” unambiguously refers only “to the physiological differences between male and female,” *id.* at 13, but with respect to assessing Title IX’s prohibition on sex discrimination, that issue is unsettled. The Supreme Court has granted certiorari in *G.G. v. Gloucester County School Board* on the question whether the Department of Education interpretation of Title IX at issue in

this Court’s *Texas* decision (No. 7:16-cv-54) should be given effect with or without deference to the agency. 822 F.3d 709 (4th Cir.), *mandate recalled, stay granted*, 136 S. Ct. 2442 (2016), *cert. granted*, No. 16-273, 2016 WL 4565643 (Oct. 28, 2016). At present, courts are split on this issue, although most recent decisions favor the federal government’s interpretation.¹⁷

Indeed, since the Supreme Court’s 1989 Title VII decision in *Price Waterhouse*, it is well-established that discrimination “because of . . . sex” is not limited to preferring males over females (or vice-versa), but includes differential treatment based on “sex-based considerations” including (but not limited to) sex stereotyping. 490 U.S. at 242. Plaintiffs’ suggestion that Title IX’s prohibition against discrimination “on the basis of sex” bars only discrimination based on anatomical and biological considerations, Franciscan Br. 13, is irreconcilable with the Supreme Court’s holding in *Price Waterhouse*—a landmark decision that Plaintiffs fail to even mention—and the “weight of circuit authority” recognizes that “discrimination against transgender individuals constitutes discrimination ‘on the basis of sex’ in the context of . . . statutes,” like Title VII, that are “analogous” to Title IX, *see Gloucester*, 822 F.3d at 727 (Davis, J., concurring) (collecting cases). Again, Plaintiffs’ narrow interpretation of discrimination on the basis of sex is wholly inconsistent with this precedent.

¹⁷ Compare *Texas*, No. 7:16-cv-54, 2016 WL 4426495, at *14 (concluding that the phrase “on the basis of sex” unambiguously refers solely to “the biological and anatomical differences between male and female students as determined at their birth”), with *Gloucester*, 822 F.3d at 720 (concluding that the phrase “on the basis of sex” is ambiguous as applied to transgender persons); *Highland*, 2016 WL 5372349, at *13 (same); *Carcaño v. McCrory*, No. 1:16-cv-236, 2016 WL 4508192, at *12-13 (M.D.N.C. Aug. 26, 2016) (applying *Gloucester*); *Students & Parents for Privacy v. U.S. Dep’t of Educ.*, No. 16-cv-4945, 2016 WL 6134121, at *19 (N.D. Ill. Oct. 18, 2016) (denying preliminary injunction because “at this early stage of this case, the Court cannot say with confidence that . . . Federal Defendants violated the APA . . . based on an interpretation of Title IX that includes gender identity within the term ‘sex’”); *Whitaker v. Kenosha Unified Sch. Dist. No. 1*, No. 16-cv-943, 2016 WL 5239829, at * 3 (E.D. Wis. Sept. 22, 2016) (concluding that the term “sex” was ambiguous as to transgender persons, and deferring to federal defendants’ interpretation).

Plaintiffs argue that the statute’s purpose should be paramount, but then fail to address the purpose of the statute at issue here—the Affordable Care Act—at all. *See* Franciscan Br. 15-16 (discussing only whether “the purpose of *Title IX* was to ensure equal opportunities in education for women” (emphasis added)). The purpose of the ACA and Section 1557 is “to expand access to [health] care and coverage and eliminate barriers to access.” 81 Fed. Reg. at 31,377. The Rule’s interpretation of sex discrimination is the interpretation that best takes into account that purpose. It is the only interpretation that protects transgender individuals from being excluded from health care opportunities on the basis of sex-related characteristics. HHS’s interpretation of Section 1557 ensures that transgender individuals are not subject to differential treatment, including denial of access to medical procedures and health insurance coverage, solely because of such sex-based considerations—namely, the fact that their gender identity differs from their birth-assigned sex.¹⁸

¹⁸ Plaintiffs’ remaining *Chevron* step-one arguments are similar to those raised before this Court in *Texas*, No. 7:16-cv-54, and they are not persuasive here. It is not particularly relevant that the Congress that enacted Title VII in 1964 and Title IX in 1972 may not have had transgender individuals in mind. *See* Franciscan Br. 15-16. While this Court’s *Texas* ruling relied on “the intent of the drafter,” 2016 WL 4426495, at *14, the statute at issue here is the Affordable Care Act, enacted in 2010. In any event, the Supreme Court has instructed that the meaning of Title VII (and, by extension, Title IX) should not be limited to what was in the minds of the legislators who drafted those statutes over fifty years ago. *See Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) (“statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed”). And contrary to Plaintiffs’ assertions, *see* Franciscan Br. 16-17, other congressional actions (or inactions) do not reinforce their view. Plaintiffs point to the 2013 amendments to the Violence Against Women Act (“VAWA”), 42 U.S.C. § 13925(b)(13)(A), but there is no evidence that Congress intended the explicit inclusion of “gender identity” in VAWA to imply that discrimination based on gender identity falls outside the meaning of discrimination “on the basis of sex.” Nor can any inference of intent be drawn from the fact that Congress has not amended Title IX or other statutes to explicitly proscribe discrimination on the basis of gender identity. Many inferences can be drawn from a failure to amend an existing statute, “including the inference that the existing legislation already incorporated the offered change.” *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (citation omitted).

b. The Rule's interpretation of Section 1557 is reasonable and entitled to deference

To the extent that the scope of Section 1557's prohibition on sex discrimination is ambiguous, the Court must proceed to *Chevron's* second step. *See City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013) (agencies are entitled to *Chevron* deference when interpreting "a statutory ambiguity that concerns the scope of the agency's statutory authority"). Review at step two is "narrow and deferential." *Alenco Commc'ns., Inc. v. FCC*, 201 F.3d 608, 620 (5th Cir. 2000). "The court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *BNSF Ry. Co. v. United States*, 775 F.3d 743, 755-56 (5th Cir. 2015). Instead, a court may reject an interpretation only if it is "manifestly contrary to the statute." *Tex. Office of Pub. Utility Counsel v. FCC*, 183 F.3d 393, 410 n.10 (5th Cir. 1999). If "the agency has offered reasonable justifications for its" interpretation, the inquiry is over. *Id.* at 412. Here, as Plaintiffs acknowledge by failing to make any arguments addressing *Chevron's* second step, they cannot demonstrate that they are likely to succeed on their claim because HHS has cogently explained the reasoning behind the Rule, and this explanation more than satisfies step two's "reasonableness requirement." *Id.*

Through a robust rulemaking process, HHS weighed the various competing interests at stake in implementing Section 1557 of the Affordable Care Act. Throughout, HHS was cognizant that "[o]ne of the central aims of the ACA is to expand access to health care and health coverage for all individuals" and that "[e]qual access for all individuals without discrimination is essential to achieving this goal." 80 Fed. Reg. at 54,194. In promulgating the Rule, HHS aimed to "help address these issues." *Id.* The notice-and-comment process confirmed that exclusion of individuals from health programs because their gender identity does not align with their sex assigned at birth was a key factor that had been raising significant barriers to health care. For

example, the Department received 303 comments from individuals in response to its Request for Information, 239 of which “were personal testimonies from transgender individuals describing their experiences of discrimination in the health care setting.” *Id.* at 54,172. And in a recent survey considered by the Department, a remarkable 70% of transgender or gender non-conforming patients reported experiencing some type of discrimination in accessing (or attempting to access) health care services.¹⁹

To address these issues, in the NPRM, the Department proposed to define the term “on the basis of sex” to include, among other things, “gender identity,” and sought comment to ensure that this interpretation would “reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination.” 80 Fed. Reg. at 54,177. The Department further noted that OCR had “previously interpreted sex discrimination to include discrimination on the basis of gender identity,” in keeping with interpretations set forth by other federal agencies, and that courts, too—“including in the context of Section 1557”—have “recognized that sex discrimination includes discrimination based on gender identity.” *See id.* at 54,176 & nn.19-21 (collecting

¹⁹ *See* HUMAN RIGHTS CAMPAIGN, HEALTHCARE EQUALITY INDEX 2014 at 4 (2014), <https://goo.gl/bXfxnb>. Materials such as this report were considered by the Department in the rulemaking process, and will be included in the administrative record that Defendants will produce in this case at the appropriate time. *See also* INSTITUTE OF MEDICINE, THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING at 61-67 (2011) (surveying barriers to accessing health care), <https://www.nap.edu/catalog/13128/the-health-of-lesbian-gay-bisexual-and-transgender-people-building>; LAMBDA LEGAL, WHEN HEALTH CARE ISN’T CARING: TRANSGENDER AND GENDER-NONCONFORMING PEOPLE at 1-2 (2010), <https://goo.gl/Zba507> (reporting that 27% of transgender survey respondents reported being refused needed care; 21% reported being subjected to harsh or abusive language by health care providers; over 15% reported experiencing the refusal of providers to touch them, or the use of excessive precautions during treatment; 20% reported being blamed for the medical problem for which they sought care; and almost 8% reported being subjected to physically rough or abusive treatment by providers).

authorities). But the Department also acknowledged that some courts have held otherwise. *See id.* at 54,176 n.21.

As the Department explained in the Rule’s preamble, “[a] significant number of commenters commended [HHS’s] inclusion of gender identity and sex stereotyping in the definition of ‘on the basis of sex’ and noted that the inclusion is consistent with a growing body of legal precedent.” 81 Fed. Reg. at 31,388. On the other hand, “a few commenters opined that the inclusion of gender identity discrimination as a form of discrimination on the basis of sex was based on erroneous interpretations of Title IX legislative history” and urged that “Congressional intent to ban sex discrimination was based only on the biological classifications of males and females.” *Id.* Some pointed “to a few recent court decisions under Title IX that rejected claims that discrimination on the basis of sex includes discrimination on the basis of gender identity.” *Id.* In addition, a few commenters expressed concerns that the Rule’s proposed definition “may infringe upon individual patients’ constitutional right to privacy [or impact their religious convictions] by requiring those patients to participate in sex-specific programs or activities with a ‘non-biological’ male or female.” *Id.*

After considering the full spectrum of these comments and authorities, HHS determined that “its inclusion of gender identity is well grounded in the law,” and “accords with well-accepted legal interpretations adopted by other Federal agencies and courts.” *Id.*; *see id.* at 31,384-85 & nn.42-43, 31,388-89 & nn.63-67 (collecting authorities). The Department explained that “[a]s the Supreme Court made clear in *Price Waterhouse v. Hopkins*, in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes.” *Id.* at 31,388 (citing 490 U.S. at 251). Consistent with these

authorities, HHS confirmed that transgender individuals are entitled to access health care that is medically indicated for them, free from discrimination based on sex-based characteristics.

The Department's construction is reasonable, and certainly is not "manifestly contrary to the statute." *Tex. Office of Pub. Utility Counsel*, 183 F.3d at 410 n.10; *see also Baylor Cty. Hosp. Dist. v. Burwell*, 163 F. Supp. 3d 372, 384 (N.D. Tex. 2016) (O'Connor, J.) ("This Court is 'mindful of the Supreme Court's repeated suggestion that HHS interpretations, in particular, should receive more respect than the mine-run of agency interpretations.'" (citations omitted)). Gender dysphoria is a medical diagnosis given to individuals who experience an ongoing "marked difference between" their "expressed/experienced gender and the gender others would assign" them. American Psychiatric Association, *Gender Dysphoria*, at 1 (2013), <http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf>. To alleviate the psychological stress that this disconnect creates, transgender individuals often undertake some level of gender transition to bring external manifestations of gender into conformity with internal gender identity. The clinical basis for gender transition, and the protocol for transitioning, are well-established. Since the 1970s, the World Professional Association for Transgender Health ("WPATH"), an internationally recognized organization devoted to the study and treatment of gender identity-related issues, has published "Standards of Care," which set forth recommendations for the treatment of gender dysphoria and the research supporting those recommendations. WPATH, *STANDARDS OF CARE FOR THE HEALTH OF TRANSEXUAL, TRANSGENDER, AND GENDER-NONCONFORMING PEOPLE* (7th ed. 2012) ("WPATH STANDARDS"), <https://goo.gl/6D8X8d>.²⁰

²⁰ It is noteworthy that in a recent decision, HHS's Departmental Appeals Board ("DAB") invalidated as unreasonable a National Coverage Determination by the Centers for Medicare &

Determinations about appropriate medical care surrounding gender transition—including not only surgical measures, but also counseling and hormone therapy, *see* 81 Fed. Reg. at 31,434—must be made by physicians and their patients on an individualized basis, *see* WPATH STANDARDS at 5, 8-9, 58, 97. The Rule protects these processes and ensures that they are not affected by unlawful discrimination. Accordingly, while the Rule does not require covered entities to provide any particular gender transition services, much less services that contravene medical judgment or religious beliefs, the Rule does prevent covered entities from engaging in discrimination with regard to the provision of health services to transgender patients. *See* 45 C.F.R. § 92.101. Likewise, the Rule does not require covered entities to provide health insurance coverage for any particular gender transition services, but rather ensures that their policies are nondiscriminatory. *See id.* § 92.207. As noted above, the Department “will not second-guess a covered-entity’s neutral nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations.” *Id.* at 31,436-37.

In sum, HHS reasonably relied on the Affordable Care Act’s purpose, and well-established legal interpretations by courts and other federal agencies, to determine that Section 1557’s prohibition on sex discrimination encompasses discrimination based on gender identity. At *Chevron* step two, “[c]ourts give agency interpretations controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.” *Zermeno*, 835 F.3d at 517 (citation

Medicaid Services that had denied Medicare coverage of all gender transition surgery as a treatment for gender dysphoria. *NCD 140.3, Transsexual Surgery*, Docket No. A-13-87, 2014 WL 2558402 (HHS DAB May 30, 2014) (included in Pls.’ App’x at 888-915). In reaching this conclusion, the DAB surveyed relevant evidence, including expert testimony, and concluded that: (1) criteria for diagnosing gender dysphoria are well-accepted in the medical profession, *id.* at *6-8; (2) surgical procedures for treating gender dysphoria are safe, *id.* at *8-11; and (3) surgical procedures can be effective treatment options in appropriate cases, *id.* at *11-15; *see also id.* at *18-22 (providing an overview of the scientific literature on which the DAB relied).

omitted). Here, the Department made a reasonable decision—one supported by an overwhelming majority of stakeholders’ comments and by well-established legal authorities—to address concerns related to sex-based discrimination in health care. This decision was made following a robust notice-and-comment procedure under a clear grant of statutory authority. Accordingly, Plaintiffs are unlikely to succeed on their claim that Section 1557 forecloses the Department’s interpretation.

2. Plaintiffs’ remaining challenges are meritless

Plaintiffs are unlikely to succeed on their claim that the Rule exceeds the Department’s statutory authority because it does not import certain exemptions Congress has provided under Title IX into the health care context. Franciscan Br. 19-22. The Rule *does* incorporate “federal statutory protections for religious freedom and conscience,” 45 C.F.R. § 92.2(b)(2)—including the Weldon, Church, and Coats amendments, and RFRA—and does not “displace . . . provisions in the ACA related to abortion services,” that is, the specific exemptions in the statutory scheme at issue here, *see* 81 Fed. Reg. at 31,379 & n.14. Indeed, while *Title IX* contains a religious exemption, *see* 20 U.S.C. § 1681(a)(3) (exempting an “educational institution which is controlled by a religious organization” under certain circumstances), and a provision ensuring “[n]eutrality with respect to abortion,” *see id.* § 1688, *Section 1557* does not, *see* 42 U.S.C. § 18116. As the Department explained, “Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.” *See* 81 Fed. Reg. at 31,380. “[S]tudents or parents selecting religious educational institutions typically do so as a matter of choice,” whereas “[i]n the health care context . . . individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions.” 81 Fed. Reg. at 31,380. This difference becomes particularly acute when “emergency circumstances” are considered. *See id.* Exempting all religious health care providers from the Rule’s prohibition on sex discrimination

“could result in a denial or delay in the provision of health care to individuals . . . with serious and, in some cases, life threatening results.” *Id.* The Department therefore opted for a “more nuanced approach” that nevertheless respects providers’ religious and conscience-based objections and, among other things, expressly references the specific abortion-related provision in the Affordable Care Act, the statute in which Section 1557 is itself contained. *See id.* at 31,379-80 & nn.14, 17-18. Because the Department has “articulate[d] a rational connection between the facts found and the choice[s] made,” and because its decisionmaking “path may reasonably be discerned,” its choices must be upheld under the Administrative Procedure Act’s “narrow” standard of review. *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974).²¹

Finally, the APA arguments pressed by the State Plaintiffs in particular, under the Constitution’s Spending Clause and Tenth Amendment, fail for reasons already addressed. Plaintiffs’ Spending Clause challenge reprises their *Chevron* step one argument. *See* States Br. 11-19 (arguing that the Rule violates the Spending Clause because the Rule’s definition of “sex” is not in accord with a biological or anatomical understanding of that term’s meaning). And Plaintiffs’ Tenth Amendment challenge, like their claim of irreparable injury, hinges on their incorrect assertions that the Rule usurps state authority over the medical profession, *see id.* at 19-23, and preempts state laws concerning abortion, *see id.* at 24. The Rule does neither. *See supra*

²¹ For the reasons explained above, *see supra* Section I, Plaintiffs’ claim that the Rule prohibits covered employers from providing their employees with religious accommodations, Franciscan Br. 22-23, is also meritless. Likewise, because the Rule expressly prohibits any application that would violate the Religious Freedom Restoration Act, 45 C.F.R. § 92.2(b)(2); *see* 81 Fed. Reg. at 31,379 & n.13, Plaintiffs’ pre-enforcement RFRA challenge to the Rule, Franciscan Br. 23-32, necessarily cannot succeed.

Section I.²² Plaintiffs’ Spending Clause and Tenth Amendment challenges are therefore predicated on the same faulty premises as their other claims, and are not likely to succeed for the same reasons.

In any event, if the Court were to find (which it should not) that Plaintiffs are likely to succeed on their claim that Section 1557’s prohibition on sex discrimination protects individuals only from discrimination based on biological or chromosomal traits, and not based on gender identity, there would be no basis for the Court to consider any of Plaintiffs’ constitutional claims, whether those addressed above or below. *See* *Nw. Austin Mun. Util. Dist. No. One*, 557 U.S. at 205; *see, e.g., Jean v. Nelson*, 472 U.S. 846, 854 (1985) (“Prior to reaching any constitutional questions, federal courts must consider nonconstitutional grounds for decision.” (citation omitted)); *Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring) (“The Court will not pass upon a constitutional question although properly presented by the record, if there is also present some other ground upon which the case may be disposed of Thus, if a case can be decided on either of two grounds, one involving a constitutional question, the other a question of statutory construction or general law, the Court will decide only the latter.”). But if the Court does not agree with Plaintiffs’ *Chevron* argument, Plaintiffs’ remaining claims fail for the reasons discussed below.

B. Plaintiffs Cannot Succeed On Their First Amendment Claim Because The Rule Does Not Compel Or Curtail Speech

“The government may not prohibit the dissemination of ideas that it disfavors, nor compel the endorsement of ideas that it approves.” *Knox v. Serv. Emps. Int’l Union, Local 1000*, 132 S. Ct. 2277, 2288 (2012). The Rule does neither. Plaintiffs’ theory to the contrary, *see* *Franciscan*

²² Moreover, as noted above, no State Plaintiff has alleged that its employee health benefit plans contain a categorical exclusion for all gender transition services. There is no basis, therefore, for Plaintiffs’ claims that “[t]he exclusions Texas and other states currently possess in their employee insurance policies related to” such services “will now be illegal under the new Rule.” States Br. 24.

Br. 33-35, rests entirely on statements in the Rule’s preamble that they take out of context. The Department’s observations that an “across-the-board categorization” of “all transition-related treatment as cosmetic or experimental” is “outdated and not based on current standards of care,” 81 Fed. Reg. at 31,429; *see id.* at 31,435, were made in the context of discussing “health-related *insurance plans* or other health-related *coverage*,” *id.* at 31,429 (emphasis added), and “equal access to health [insurance] *coverage*,” *id.* at 31,435 (emphasis added). Accordingly, while the Rule prohibits covered entities from categorically excluding or limiting insurance coverage for all health services related to gender transition, *see* 45 C.F.R. § 92.207(b)(4), it places no parallel (or even similar) restrictions on what medical advice physicians can provide.

Thus, notwithstanding Plaintiffs’ allegations, the Rule does not prohibit health care providers from expressing their medical opinions and speaking for or against medical transition procedures, to patients or otherwise.²³ Plaintiffs also assert that “the Rule mandates revisions to health-care professionals’ written policies, requiring express affirmance that transition-related procedures will be provided,” Franciscan Br. 36-37, and that the Rule requires providers to use a patient’s preferred name and gender, *id.* at 37. But fundamentally, the Rule does not “regulate *speech* on the basis of its expressive content.” *Cf. DeAngelis*, 51 F.3d at 597 n.7 (emphasis added). Accordingly, even assuming the Rule would have the effects Plaintiffs allege, Plaintiffs’ free

²³ Of course, the Rule may prohibit discriminatory harassment that masquerades as the expression of medical judgment without running afoul of the First Amendment. *See, e.g., Jenson v. Eveleth Taconite Co.*, 824 F. Supp. 847, 884 (D. Minn. 1993) (“Title VII may legitimately proscribe conduct, including undirected expressions of gender intolerance, which create an offensive working environment. That expression is ‘swept up’ in this proscription does not violate First Amendment principles.” (quoting *R.A.V. v. City of St. Paul*, 505 U.S. 377, 389 (1992))). Although the Fifth Circuit has, in dicta, suggested that a harassment claim “founded solely on verbal insults” might raise First Amendment concerns, *DeAngelis v. El Paso Mun. Police Officers Ass’n*, 51 F.3d 591, 596-97 (5th Cir. 1995), such concerns could—and, indeed, could only—be evaluated on a case-by-case basis. More to the point, Plaintiffs have indicated no intent to engage in harassment.

speech claim fails. The purportedly “compelled speech to which [Plaintiffs] point is plainly incidental to the [Rule’s] regulation of *conduct*”—its prohibition on discrimination—“and ‘it has never been deemed an abridgment of freedom of speech . . . to make a course of conduct illegal merely because the conduct was in part . . . carried out by means of language, either spoken, written, or printed.’” *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* (“*FAIR*”), 547 U.S. 47, 62 (2006) (emphasis added) (quoting *Giboney v. Empire Store & Ice Co.*, 336 U.S. 490, 502 (1949)). The particular example the Supreme Court provided in *FAIR* likewise arose in the antidiscrimination context: “Congress . . . can prohibit employers from discriminating in hiring on the basis of race. The fact that this will require an employer to take down a sign reading ‘White Applicants Only’ hardly means that the law should be analyzed as one regulating the employer’s speech rather than conduct.” *Id.* (citation omitted).

C. Plaintiffs Have Not Met Their Heavy Burden In Attempting A Facial, Pre-Enforcement Vagueness Challenge

Plaintiffs have failed to demonstrate a likelihood of success on the merits of their Fifth Amendment void-for-vagueness challenge as well. Plaintiffs face a “heavy burden” in seeking to demonstrate that the Rule is facially void for vagueness. *Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 548 (5th Cir. 2008); *see id.* at 547 (“In the context of pre-enforcement review, . . . examining facial vagueness is often difficult, perhaps impossible, because facts are generally scarce.”). That is particularly so given that the Rule does not involve criminal consequences. *See Groome Res. Ltd., L.L.C. v. Par. of Jefferson*, 234 F.3d 192, 217 (5th Cir. 2000). Thus, analyzing whether the Rule is “so vague and indefinite as really to be no rule at all,” *id.* (citation omitted), Plaintiffs are highly unlikely to succeed. Plaintiffs base their claim of vagueness almost entirely on the preamble, *see* Franciscan Br. 39-43, ignoring that the Rule itself speaks in concrete, digestible terms modeled precisely on those found in the longstanding civil rights statutes that

Section 1557 cites.²⁴ Plaintiffs highlight that, with respect to certain issues, HHS declined to provide specific examples of what might constitute discrimination. Franciscan Br. 40-41. Yet Plaintiffs cite no case supporting the proposition that nondiscrimination provisions must be accompanied by concrete examples, or that an agency declining an invitation to provide examples somehow itself renders a regulation unconstitutionally vague. Plaintiffs counter that the Rule leaves the agency with too much discretion, but “with pre-enforcement challenges, such as this, ‘the speculative danger of arbitrary enforcement does not render the ordinance void for vagueness.’” *Miata v. City of Daytona Beach*, No. 6:14-cv-1428, 2015 WL 506287, at *5 (M.D. Fla. Feb. 6, 2015) (quoting *Vill. of Hoffman Estates v. Flipside*, 455 U.S. 489, 503 (1982)). Nor can Plaintiffs succeed simply by coming up with hard cases or attempting to tease inconsistency from the Rule. *See* Franciscan Br. 40-41. “[I]t will always be true that the fertile legal ‘imagination can conjure up hypothetical cases in which the meaning of (disputed) terms will be in . . . question,’ but that alone does not render the rule void for vagueness.” *Gosney v. Sonora Indep. Sch. Dist.*, 603 F.2d 522, 526 (5th Cir. 1979) (quoting *Am. Commc’ns Ass’n v. Douds*, 339 U.S. 382, 412 (1950)).

D. Plaintiffs’ Substantive Due Process Claim Fails

Plaintiffs are unlikely to prevail on their substantive due process claim, Franciscan Br. 44-47, for the reasons already set forth. Plaintiffs’ claim centers on their assertion that the Rule requires providers to “perform[] . . . medical procedures that violate their conscience, particularly with regard to abortion and sterilization.” *Id.* at 44. But as explained above, the Rule cannot be

²⁴ Compare 45 C.F.R. § 92.101(a) (“an individual shall not, on the basis of race, color, [or] national origin . . . , be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which [the Rule] applies”) with, e.g., 42 U.S.C. § 2000d (Title VI) (“No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”).

applied so as to “require[]” an “individual . . . to perform or assist in the performance of any part of a health service program . . . if his performance or assistance . . . would be contrary to his . . . moral convictions,” 42 U.S.C. § 300a-7(d) (Church Amendment); *see also id.* § 300a-7(b). Plaintiffs lean heavily on these Church Amendment provisions, *see* Franciscan Br. 46-47, without acknowledging that the Rule explicitly incorporates them, *see* 45 C.F.R. § 92.2(b)(2)—perhaps because taking them into account confirms that Plaintiffs’ substantive due process claim is meritless.

IV. THE BALANCE OF THE EQUITIES AND THE PUBLIC INTEREST FAVOR DENYING PRELIMINARY INJUNCTIVE RELIEF

Because Plaintiffs have not made the threshold showings of either irreparable harm or a likelihood of success on the merits, there is no need for the Court to consider the balance of equities and public interest. *See, e.g., Jackson*, 556 F.3d at 360. However, even if the Court were to do so, this would be further grounds for denying Plaintiffs’ motions because these factors tip in Defendants’ favor. Plaintiffs have failed to demonstrate that any alleged irreparable injuries outweigh the harm that the preliminary injunction would cause Defendants and unrepresented third parties, and that granting the injunction would be in keeping with the public interest. *See Star Satellite, Inc. v. City of Biloxi*, 779 F.2d 1074, 1079 (5th Cir. 1986); *Southdown, Inc. v. Moore McCormack Res., Inc.*, 686 F. Supp. 595, 596 (S.D. Tex. 1988).

Plaintiffs have not made any showing of injury here, let alone injury that is substantial, imminent, and irreparable. Against this non-existent showing of harm weighs the significant public interest in achieving Section 1557’s goals of eliminating discrimination in healthcare. It is well-established that violations of federal civil rights statutes constitute irreparable harm as a matter of law. *See United States v. Hayes Int’l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969); *Silver Sage Partners, Ltd. v. City of Desert Hot Springs*, 251 F.3d 814, 827 (9th Cir. 2001); *Roberts v.*

Colo. State Bd. of Agric., 998 F.2d 824, 833 (10th Cir. 1993); *Rogers v. Windmill Pointe Vill. Club Ass’n*, 967 F.2d 525, 528 (11th Cir. 1992). More generally, there is “inherent harm to an agency” in preventing it from enforcing statutes and regulations that “Congress found it in the public interest to direct that [it] develop and enforce.” *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008).

In this regard, while the Non-State Plaintiffs seek to preliminarily enjoin defendants from enforcing the Rule’s prohibition on sex discrimination “against Plaintiffs” and related entities,²⁵ it is possible to read the State Plaintiffs’ proposed order as requesting preliminary injunctive relief on behalf of non-plaintiffs as well.²⁶ As the Non-State Plaintiffs apparently recognize, it is black-letter law that preliminary injunctive relief should be only as broad as necessary to prevent irreparable harm to the plaintiffs pending an opportunity for a full adjudication on the merits. *See, e.g., Califano v. Yamasaki*, 442 U.S. 682, 702 (1979); *Lion Health Servs., Inc. v. Sebelius*, 635 F.3d 693, 703 (5th Cir. 2011); *Hernandez v. Reno*, 91 F.3d 776, 781 (5th Cir. 1996).²⁷ For all the reasons explained above, Plaintiffs are entitled to no relief, but if the Court disagrees, at this juncture the Court can only preliminarily enjoin Defendants from enforcing the two aspects of the Rule that Plaintiffs challenge—its prohibition against discrimination on the bases of gender identity and termination of pregnancy—as to Plaintiffs. *See Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) (a preliminary injunction’s “limited purpose” is “merely to preserve the relative

²⁵ *See* [Proposed] Order Granting Pls.’ Mot. for Partial Summ. J. or, in the Alternative, for Prelim. Inj. (email from Luke Goodrich to Judge O’Connor’s Chambers, Oct. 22, 2016, 12:12 am Central).

²⁶ *See* [Proposed] Order Granting Pls.’ Mot. For Prelim. Inj. at 2 (Oct. 21, 2016), ECF No. 22-1.

²⁷ Defendants acknowledge that, in a different context, this Court recently reached a different conclusion, *see, e.g., Order, Texas*, No. 7:16-cv-54 (N.D. Tex. Nov. 20, 2016), ECF No. 100, but for the reasons explained above and in the briefing in that case, Defendants respectfully disagree.

positions *of the parties* until a trial on the merits can be held” (emphasis added)); *League of Women Voters of the United States v. Newby*, 838 F.3d 1, 15 (D.C. Cir. 2016) (“A preliminary injunction d[oes] not vacate” an administrative action, “but merely prohibits the [agency] from giving [it] effect, pending entry of the final judgment.”). The role of an injunction is not to “enjoin all possible breaches of the law,” but to “remedy the specific harms” allegedly suffered by the plaintiffs themselves. *Zepeda v. INS*, 753 F.2d 719, 728 n.1 (9th Cir. 1983) (quoting, *inter alia*, *Hartford-Empire Co. v United States*, 323 U.S. 386, 409 (1945)); *see id.* (“This is particularly true when . . . a preliminary injunction is involved.”). Here, there has been no showing that non-plaintiff relief is required to protect Plaintiffs’ own interests during the pendency of these proceedings.

Finally, Plaintiffs’ delay in seeking relief further “militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency to the request for injunctive relief.” *Ellipse Commc’ns, Inc. v. Caven*, No. 3:07-cv-1922, 2009 WL 497268, at *2 (N.D. Tex. Feb. 26, 2009) (O’Connor, J.). The Rule was published on May 18, 2016, but Plaintiffs waited to file suit until more than three months later, on August 23. Plaintiffs then waited an additional month, until September 26, to serve the United States Attorney for the Northern District of Texas, and it was almost yet another month before they moved for a preliminary injunction on October 21. Not only, then, are Plaintiffs’ assertions of irreparable injury speculative; they also have come too late. *See ADT, LLC v. Capital Connect, Inc.*, 145 F. Supp. 3d 671, 698 (N.D. Tex. 2015) (“Where parties fail to explain or justify the delay between the facts underlying the need for

the preliminary injunction and the motion for the injunction, courts readily decline motions to enjoin for lack of urgency.”).²⁸

CONCLUSION

Defendants respectfully request that the Court deny Plaintiffs’ motions for preliminary injunction.

Dated: November 23, 2016

Respectfully Submitted,

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²⁸ See, e.g., *Innovation Ventures, LLC v. Ultimate Lifestyles, LLC*, No. 08-cv-232, 2009 WL 1490588, at *3 (E.D. Tex. May 27, 2009) (nine-month delay); *Gonannies, Inc. v. Goaupair.com, Inc.*, 464 F. Supp. 2d 603, 609 (N.D. Tex. 2006) (six-month delay).

CERTIFICATE OF SERVICE

I hereby certify that on November 23, 2016, I electronically filed a copy of the foregoing. Notice of this filing will be sent via email to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

/s/ Adam Grogg
ADAM GROGG